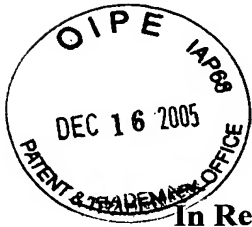


DOCKET NO.: CEPH-2249/CP241

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Craig Heacock, et al.

Application No.: 10/616,776

Filing Date: July 10, 2003

Confirmation No.: 1994

Group Art Unit: 1615

Examiner: Not Yet Assigned

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

**DECLARATION BY ATTORNEY IN SUPPORT OF PETITION TO MAKE
SPECIAL BECAUSE OF ACTUAL INFRINGEMENT (MPEP § 708.02)**

I, S. Maurice Valla, Woodcock Washburn LLP, One Liberty Place, 46th Floor, Philadelphia PA, 19103, Registration No. 43,966, Telephone No. 215-564-3100, am the attorney of record for Applicants and make the following declarations.

1. I have made a rigid comparison of the product and method of use referred to in the accompanying declaration of Craig S. Heacock, Ph.D. with the claims of this application.
2. In my opinion, the product and method of use referred to in the accompanying declaration of Craig S. Heacock, Ph.D. is within the scope of at least claims 134 and 137 to 145 on file in this application.
3. In my opinion, the ANDA that Ranbaxy Laboratories Limited has already filed constitutes an act of actual infringement of at least claims 134 and 137 to 145 under Section 271(e)(2) because the ANDA constitutes an application under Section 505(j) of the Federal

Food, Drug, and Cosmetic Act for a drug and use thereof recited in these claims, and said application was submitted to obtain approval under said Act to engage in the commercial manufacture, use, and sale of the claimed drug product and use. Since the Ranbaxy ANDA has already been filed, the instant application could immediately be asserted upon issue.

4. I have a knowledge of the pertinent prior art by virtue of prosecution. All such material art is provided to the Examiner as

☒ having been filed

☒ being filed

in a respective Information Disclosure Statement. I believe the closest prior art to be U.S. Patent No. RE37,516, cited in the Information Disclosure Statement submitted in this application on October 15, 2003, as well as U.S. Published Application 2004/0167225 A1 and the Provigil® modafinil product (referenced in the instant application in the paragraph bridging pages 5-6, and described in the FDA approved label), cited in the Supplementary Information Disclosure Statement filed herewith.

5. I believe all the claims presently on file in this application are allowable.

6. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the


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United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: December 15, 2005



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